Generic Questionnaire for Biopharmaceutical Production Candidates
Mammalian Cell Products

Principal Investigator:
Institution:

1. What amount(s) of delivered product(s) is desired?
   A. Non-GMP (laboratory grade)
      i) What level of purity is desired?

   B. GMP (clinical grade)
      i) What is the ultimate use: parenteral, topical, ex vivo use, as part of a device?
      ii) If the current request is for Phase I clinical material, please indicate the projected estimate for the Phase I trial and also describe the number of patients, schedule and dose range for the Phase I trial. Please also describe the number of patients you project for follow-on Phase II trials.

2. Please provide details of your construct or starting materials and information on the derivation of the cell line.

3. What expression systems have been tried for this product?

4. What expression system have you selected for production?

5. Do you have a qualified master cell bank? A working cell bank? An accession bank?

6. Please provide details of your production system, including media requirements. Include media and additives that should be avoided.

7. Please provide details of your current purification scheme.

8. What is the current yield of production? Of purification?

9. What is the largest amount of material that you have produced in your laboratory in a single production batch? What is the largest amount that you have purified in your laboratory in a single batch?

10. Do you have material to supply as a reference standard? Please describe the quantity available, and its purity, potency, and stability.

11. Virus inactivation or elimination may involve treatment with acid, detergent, or filtration. Please provide information, if available, about the stability of your product(s) under these conditions.

12. Describe the desired specifications & assays for identity, purity, and potency of this product.

13. Do you have any material to supply as bulk biologic substance for preliminary pharmacology and toxicology studies? If so, how much is available for these studies?

14. Are there concerns about the physical properties (e.g., folding, soluble or secreted form, dimerization) and stability of your product?

15. Do you have reproducible assays (including identity, purity, and potency) for your product? Please provide details of these assays.

16. Do you have a proposed list of release criteria for your product?

17. Are there issues of formulation and vialing that must be resolved?

18. In what form (lyophilized powder, formulated product, etc.) and fill size and concentration do you want for the final product? What is the final product formulation? Are special types of vials required?

19. Please indicate the largest single dose expected to be used in the clinical trial. Please indicate doses, routes and schedules to be used in the clinical trial.

20. Do you already have information about estimated costs associated with this project?

21. Have you identified any possible sources of production with any commercial firms? Please provide any details that you have.

22. Are there any safety issues connected with the production, purification, and/or handling of your product?

23. What are the intellectual property issues concerning your product(s)?

24. Sometimes, proposed projects are an improvement or modification of an existing approach. In these cases, this information may affect significantly affect our analysis of feasibility, cost, and other production issues. Of course, this information may also be important in consideration of intellectual property issues. To the extent that you are aware, please provide a brief summary of the nature of any such antecedents or other approaches that may appear closely related to the project you propose. Please provide published references if they are available.

25. Have you had or are you preparing to have any meeting with Regulatory Agencies such as a pre-IND meeting with the USFDA? If yes, please indicate the type of meeting, the regulatory agency, and the date or proposed date.

26. Who will sponsor the IND for the Clinical Study?